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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,281	09/23/2003	Robert W. Esmond	4012.0373-01000	6560

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,281

Applicant(s)

ESMOND ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-19 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-19 and 21-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicant's amendment filed Dec. 22, 2004. The claims 1-2, 7-19 and 21-28 are pending and presented for the examination.

Claim Rejections - 35 USC § 112

2. 112 rejection is substantially same as previous rejection cited in 1st non-final office action(8/23/04).

Claim Rejections - 35 USC § 102

3. 102 rejection is substantially same as previous rejection cited in 1st non-final office action(8/23/04).

4.

Response to Arguments

5. Applicant's arguments filed Dec 22, 2004 have been fully considered but they are not persuasive.

- a. Firstly, applicants traverse is based on different interpretation of the claimed term "prevention" as "tendering to defeat or hinder and thus, prevent from starting or moving forward, to check, retard, impede, delay, stop, interrupt, thwart" not necessarily as "primary or complete prevention"(see remarks, page 2). Applicants also allegedly state that prevention may also be achieved by delaying the onset of the disease or slowing the course of the disease. As acknowledged by applicant, the term "prevention" can be defined as "forestall the disease completely". Applicants state that said discovery and reduction in

insulin levels could be able to prevent the Alzheimer's disease, where applicants also acknowledge the fact that the instant invention is related only to the method of partial prevention of Alzheimer's disease which is achieved by reduction of level of circulating insulin level, but not to all methods of prevention achieved by utilizing unknown or other known mechanisms(pathogenesis) associated with the induction of Alzheimer's disease.

However, the claims must be given their broadest reasonable interpretation. Therefore, the interpretation of claims (i.e. prevention of Alzheimer's diseases) should be made based on the full definition of the term "prevention" including "forestall Alzheimer's disease completely" wherein the claims become not enabled.

Emphasis is made again that it is well recognized and acknowledged by the skilled artisan in the medical industry that prevention of Alzheimer's disease is not credible absent definite data, see PTO-892 for supporting documents. The state of the art clearly recognizes that there is no cure or prevention of Alzheimer's disease but the treatment of symptoms of Alzheimer's diseases. In response to applicant allegedly statement regarding the supporting documents cited by the examiner(i.e. Gottfires or Mandelkow, published in 1994), which is not good indications of the state of the art since it has old publication date. The examiner encloses other supporting documents(with recent publication date) which acknowledge the state of the art and support the examiner's allegation

regarding lack of enablement for preventing Alzheimer's diseases, see PTO-892, e.g. Antuono(2001) or Fact sheet for Alzheimer's dx(2004).

Applicants fail to show certain features of applicant's invention, such that the features upon which applicant relies (i.e., to lessen the symptoms or delay the progression of the disease) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). If applicants like to limit the scope of the claims to a method of delaying the progression of the disease, the claims must be amended to recite the said features and to limit the scope as set forth.

Thus, the above 112 rejection(failing enabling requirement) is hereby maintained.

b. In response to applicant's argument regarding 102 rejection, applicants argue that the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.

It is noted that the extrinsic evidence are available and quoted to support inherent feature(i.e. prophylactic utility was inherently met in same dosage regimen used to treat diabetic mellitus or reduction in insulin level) is enclosed in PTO-892, see Craft et al(Neurology 1998, Jan). Craft et al teach that patient with Alzheimer's disease have elevations of fasting plasma insulin level that are

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associated with disrupted brain insulin metabolism. Both plasma and CSF insulin levels are abnormal in AD patient when compared with healthy adults. Thus, the said extrinsic evidence supports the protective utility as the claimed invention via correcting insulin level and treating abnormal insulin level(or ratio).

Thus, the above 102 rejection(inherency) is hereby maintained.

Conclusion

1. No claim is allowed.
2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER


Vickie Kim
April 13, 2005
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